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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,732	11/09/2001	John Matthew Swoyer	P-10110.00	8088

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EXAMINER	
BRADFORD, RODERICK D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,732	SWOYER ET AL.	
	Examiner	Art Unit	
	Roderick Bradford	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on March 15, 2004 have been fully considered but they are not persuasive.

The applicant argues that the "tines" are conductive and are a part of the electrode structure in Kroll and that Kroll does not disclose that a tine element array is positioned on the lead proximal to an electrode array. However this is not persuasive since applicant has not stated that the tines are not conductive and also the Kroll reference shows the electrode tip (25) and the extension members (24) as separate elements. The extension members are extending proximally from the electrode; also figures 5, 6, and 9 further illustrate this.

Claim Rejections – 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-8, 11, 13-18, 20, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. U.S. Patent No. 5,257,634.

Referring to claims 1, 11, 33 and 35, Kroll discloses a medical electrical lead for electrical stimulation of body tissue adapted to be introduced through and released into the body employing an introducer having an introducer lumen comprising:

- A lead body extending between lead proximal and distal ends

- P proximal connector elements formed in a connector array in a proximally segment of the lead body (29)
- P stimulation electrodes arranged in an electrode array extending proximally from the lead distal end through a distal segment of the lead body (FIG. 3)
- A plurality of M tine elements formed in a tine array extending through a segment of the lead proximal to the electrode array, each tine element comprising N flexible, pliant, tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end (FIG. 3), whereby M x N tines are adapted to be folded inward against the lead body when fitted and constrained by the lumen of an introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally and release the tines to inhibit axial dislodgement of P stimulation electrodes (column 3, lines 52-62).

Referring to claims 3 and 13, wherein the tines of the tine elements are formed of a flexible implantable grade superelastic alloy (column 4, lines 25-29).

Referring to claims 4 and 14, wherein the tine attachment sites of the M tine

elements are separated longitudinally along the lead body in the tine element array by a distance that is substantially equal to or exceeds the tine length when folded proximally against the lead body so that the tines are not overlapping (FIG. 7).

Referring to claims 5 and 15, wherein the tine attachment sites of each of the M tine are disposed in a common circumference of the lead body, offset from one another around the common circumference such that the tine free ends of the tines of each adjacent tine element engage against body tissue at a radially and axially separated points along the tine element array (FIG. 6).

Referring to claims 6 and 16, wherein the tine lengths and the tine widths are selected to enable the more distal N tines of more distal tine elements of the tine element array to be folded proximally alongside and interleaved with the adjacent more proximal tines of more proximal tine elements (FIG. 8).

Referring to claims 7, 8, 17 and 18, wherein N tines of the M tine elements are equal in number (FIG. 3).

Referring to claims 10 and 20, wherein P=1 (FIG. 3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. U.S. Patent No. 5,257,634.

Referring to claims 2 and 12, Kroll discloses the claimed invention except for wherein the tines of the tine elements are formed of a flexible bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds. It would have been obvious matter of design choice to one skilled in the art to modify the system and teachings of Kroll to have tines that are formed of a flexible bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds, since the applicant does not disclose that tines formed of a flexible bio-compatible plastic provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any tines, such as the tines as taught by Kroll as a means of placing tines in the body.

7. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. U.S. Patent No. 5,257,634 in view of Bush et al. U.S. Patent No. 5,282,845.

Referring to claims 9 and 19, Kroll fails to disclose wherein $P > 1$, and at least on

the P stimulation electrodes comprises an elongated, flexible electrode adapted to assume a curve when implanted in relation to the body. However, Bush discloses wherein P > 1, and at least on the P stimulation electrodes comprises an elongated, flexible electrode adapted to assume a curve when implanted in relation to the body (FIG. 1) as a means to more easily stimulate different body tissue.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teaching of Kroll to include wherein P > 1, and at least on the P stimulation electrodes comprises an elongated, flexible electrode adapted to assume a curve when implanted in relation to the body, as taught by Bush, as a means to more easily stimulate different body tissue.

8. Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. U.S. Patent No. 5,257,634 in view of Borkan et al. U.S. Patent No. 6,510,347.

Referring to claims 34 and 36, Kroll fails to disclose wherein the lead body further comprises a second proximal connector element, a ring shaped electrode spaced apart proximally from the distal wire coil electrode, and a second lead conductor extending between the second proximal element and the distal ring shaped electrode. However, Borkan discloses wherein the lead body further comprises a second proximal connector element, a ring shaped electrode spaced apart proximally from the distal wire coil electrode, and a second lead conductor extending between the second proximal element and the distal ring shaped electrode (column 4, lines 46-55 and column 5, lines

48-56) as a means to ensure efficient power is being provided to each of the stimulation electrodes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Kroll to include wherein the lead body further comprises a second proximal connector element, a ring shaped electrode spaced apart proximally from the distal wire coil electrode, and a second lead conductor extending between the second proximal element and the distal ring shaped electrode, as taught Borkan, as a means to ensure efficient power is being provided to each of the stimulation electrodes.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R.B.

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700